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APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P060019 **3/16/07**	Therapy™ Cool Path™ Ablation Catheter and IBI 1500T9 RF Ablation Generator	Irvine Biomedical, Inc. Irvine, CA 92614	Approval for the Therapy™ Cool Path™ Ablation Catheter and IBI 1500T9 RF Ablation Generator. The Therapy™ Cool Path™ Ablation Catheter is intended for use with a compatible external infusion pump and the IBI 1500T9 Radiofrequency (RF) Generator at a maximum of 50 watts. The catheter is intended for creating endocardial lesions during cardiac ablation procedures (mapping, stimulation and ablation) for the treatment of typical atrial flutter. The IBI 1500T9 RT Ablation Generator is intended for use with compatible St. Jude Medical temperature controlled ablation catheters for creating endocardial lesions to treat cardiac arrhythmias (i.e. supraventricular tachycardias, and atrial flutter). The generator is internally limited to 50 watts when used with the Therapy™ Cool Path™ catheters. A compatible external infusion pump must be connected when used with Therapy™ Cool Path™ catheters.
P880086/S123 **3/16/07** **180-Day**	Victory® AF DR Pulse Generator Model 5382	St. Jude Medical Sylmar, CA 91342	Approval for the Victory® AF DR Pulse Generator Model 5382.
P880086/S139 **3/29/07** **180-Day**	Zephyr Pulse Generators Models: XL DR 5826, DR 5820 and SR 5620	St. Jude Medical Sylmar, CA 91342	Approval for the Zephyr Pulse Generators Models: XL DR 5826, DR 5820 and SR 5620. The device is indicated in the following permanent conditions, when associated with symptoms including, but not limited to: syncope, presyncope, fatigue, disorientation, or any combination of those symptoms. Rate modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-chamber pacing (Models 5826, 5820 only) is indicated for those patients exhibiting: sick sinus syndrome, chronic symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, or symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular pacing is indicated for patients with significant bradycardia and: normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. AF Suppression (Models 5826, 5820

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			only) is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.
P930038/S048 3/15/07 135-Day	Angio-Seal™ Vascular Closure Device	St. Jude Medical, Inc. Minnetonka, MN 55345	Approval for use of an alternate collagen crusher.
P950022/S034 3/8/07 Real-Time	Riata, Riata ST, and Riata ST Optim Lead Families	St. Jude Medical Cardiac Rhythm Management Division Sylmar, CA 91342	Approval for the following changes: 1)Modification to the crimp slug weld tab 2) Modification to the distal header assembly 3) Modification to the PTFE liner in the IS-1 connector leg 4) Removal of the PTFE liners in the two DF-1 connector legs 5) Addition of a DF-1 plug accessory to the lead package 6) Addition of an extra-soft stylet accessory to the lead package 7) Minor modifications to the User Manual 8) Modified radius specification for the spring stopper component.
P950037/S048 3/8/07 Real-Time	Dextrus Steroid-Eluting Active-Fixation Endocardial Pacing Lead Models 4135, 4136, and 4137	Biotronik, Inc. Lake Oswego, OR 97035	Approval for an additional trade name for the market approved Setrox S Lead, as well as minor changes to the accessories, packaging, and labeling. The device, as modified, will be marketed under the trade name Dextrus, and labeled for distribution by Guidant. The Dextrus lead is indicated for permanent pacing and sensing in either the right atrium or right ventricle in conjunction with implantable pulse generators with IS-1 headers.
P950037/S049 3/26/07 Real-Time	Cylos DR/DR-T/VR, Philos DR/DR-B/SR/SR-B/SLR/DR-T, Axios DR/SR Philos II Dr/DR-T/SR, and Protos DR-CLS/VR-CLS Implantable Pacemaker Pulse Generators	Biotronik, Inc. Lake Oswego, OR 97035	Approval for: 1) updates to the integrated circuit used for electrogram sensing and non-rate responsive pacemaker timing, 2) modifications to the electronic module, and 3) implementation of multi-lingual labeling.
P960040/S144 3/29/07 Special	Vitality Implantable Cardioverter Defibrillators and Contak Renewal	Guidant Corporation Cardiac Rhythm Management St. Paul, MN 55112	Approval for the following changes for the Vitality and Contak Renewal families of defibrillators: 1) Require the reed switch component supplier to expose 100% of the components to a high magnetic field condition of minimum of 30mT, 10 cycles with 1

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	Cardiac Resynchronization Therapy Defibrillators		second duration prior to shipping to Guidant. 2) Apply an enhanced quality test of 30mT through 30 cycles and verify the reed switch is open after removing the device from the magnetic field, to all devices currently held under a Stop Action Notice (SAN).
P980016/S094 **3/15/07** **Real-Time**	EnTrust 35J ICD (D154ATG, D154DRG, D154VRC), Virtuoso ICD (D154AWG, D154VWC) and Concerto ICD (C154DWK)	Medtronic, Inc. Cardiac Rhythm Management Shoreview, MN 55126	Approval for minor design changes to the battery connector module for EnTrust 35J, Concerto, and Virtuoso ICDs.
P980016/S095 **3/26/07** **Real-Time**	Medtronic® Concerto® Model C154DWK and Virtuoso® Models D154AWG/D154VWC	Medtronic, Inc. Cardiac Rhythm Management Shoreview, MN 55126	Approval for a design change to the 9-Pin Filtered Feedthrough (FFT) of the Medtronic® Concerto® Model C154DWK and Virtuoso® Models D154AWG/D154VWC devices.
P980037/S020 **3/28/07** **180-Day**	Possis AngioJet® Rheolytic™ Thrombectomy System	Possis Medical, Inc. Minneapolis, MN 55433	Approval for the Spiroflex VG Catheter The device, as modified, will be marketed under the trade name The AngioJet® Rheolytic™ Thrombectomy System: Spiroflex™ VG Rapid Exchange Rheolytic Thrombectomy Catheter and is indicated for removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions in vessels ≥ 3 mm in diameter prior to balloon angioplasty or stent placement.
P980037/S021 **3/6/07** **Real-Time**	Possis AngioJet® Rheolytic™ Thrombectomy System	Possis Medical, Inc. Minneapolis, MN 55433	Approval for manufacturing changes to the AngioJet Pump Set piston, sensor cup and boot.
P010012/S036 **3/23/07** **180-Day**	CONTAK RENEWAL 1/3/3HE CRT-D Devices	Guidant Corporation St. Paul, MN 55112	Approval for the CONSULT Software Model 2845 v2.10 to be used to enable the ability to program the V-V timing interval in the Contak Renewal Model H135; Contak Renewal 2 Models H170 and 175; and Contak Renewal 3 HE Models H177 and H179 CRT-D devices.
P010012/S146 **3/28/07** **Real-Time**	Contak and Renewal Families of CRT-Ds	Guidant Corporation Cardiac Rhythm Management St. Paul, MN 55112	Approval for the Latitude System Software, version 2.1 (Model 6488) that contains Regulated Application Server (RAS) software, version 2.1.1 and Web application Server (WAS) software, version 2.1.1.

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P010012/S149 **3/29/07** **Special**	Vitality Implantable Cardioverter Defibrillators and Contak Renewal Cardiac Resynchronization Therapy Defibrillators	Guidant Corporation Cardiac Rhythm Management St. Paul, MN 55112	Approval for the following changes for the Vitality and Contak Renewal families of defibrillators: 1) Require the reed switch component supplier to expose 100% of the components to a high magnetic field condition of minimum of 30mT, 10 cycles with 1 second duration prior to shipping to Guidant. 2) Apply an enhanced quality test of 30mT through 30 cycles and verify the reed switch is open after removing the device from the magnetic field, to all devices currently held under a Stop Action Notice (SAN).
P010031/S063 **3/26/07** **Real-Time**	Medtronic® Concerto® Model C154DWK and Virtuoso® Models D154AWG/D154VWC	Medtronic, Inc. Cardiac Rhythm Management Shoreview, MN 55126	Approval for a design change to the 9-Pin Filtered Feedthrough (FFT) of the Medtronic® Concerto® Model C154DWK and Virtuoso® Models D154AWG/D154VWC devices.
P010068/S009 **3/21/07** **180-Day**	Navistar® RMT DS Diagnostic/Ablation Deflectable 8mm Tip Catheter, Model D-1259-xx	Biosense Webster, Inc. Diamond Bar, CA 91765	Approval for adding remote magnetic navigation technology to the previously approved catheter. The device, as modified, will be marketed under the trade name NaviStar® RMT DS Diagnostic/Ablation Deflectable 8mm Tip Catheter and is indicated for catheter-based atrial and ventricular electrophysiologic mapping (stimulation and recording), and when used with the Stockert 70 radiofrequency generator (with software version 001/033 or higher) for the treatment of type I atrial flutter in patients 18 or older. The NaviStar® RMT DS Catheter provides location information when used with the Carto™ RMT EP Navigation System. The NaviStar® RMT DS Diagnostic/Ablation Steerable Catheter is only for use with the Stereotaxis Magnetic Navigation System (MNS). Compatibility with the Stereotaxis Cardiodrive® has not been determined.
P040014/S006 **3/16/07** **Real-Time**	IBI Therapy™ Cardiac Ablation System	Irvine Biomedical, Inc. Irvine, CA 92614	Approval for a new RF generator, which includes software and hardware modifications to the previously approved RF generator. The device, as modified, will be marketed under the trade name Therapy™ Ablation Catheter and IBI 1500T9 RT Ablation Generator. The Therapy™ Ablation Catheter is indicated for mapping and for use with the IBI 1500T9 Radiofrequency (RF) Generator at a maximum of 50 watts for: interruption of accessory atrioventricular (AV) conduction pathways associated with tachycardia; the treatment of AV nodal re-entrant tachycardia

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			(AVNRT); or creation of complete AV nodal block in patients with a difficult to control ventricular response to an atrial arrhythmia. The IBI 1500T9 RF Ablation Generator is intended for use with compatible St. Jude Medical temperature controlled ablation catheters for creating endocardial lesions to treat cardiac arrhythmias (i.e. supraventricular tachycardias, and atrial flutter). The generator is internally limited to 50 watts when used with the Therapy™ Ablation Catheters.
P040042/S008 **3/16/07** **Real-Time**	Therapy™ Dual 8™ Cardiac Ablation System	Irvine Biomedical, Inc. Irvine, CA 92614	Approval for a new RF generator, which includes software and hardware modifications to the previously approved RF generator. The device, as modified, will be marketed under the trade name Therapy™ Dual 8™ Ablation Catheter and IBI 1500T9 RF Ablation Generator. The Therapy™ Dual 8™ Ablation Catheter is intended for use with the IBI 1500T9 Radiofrequency (RF) Ablation Generator at a maximum of 100 watts. The catheter is intended for creating endocardial lesions during cardiac ablation procedures (mapping, stimulation and ablation) for the treatment of typical atrial flutter. The IBI 1500T9 RF Ablation Generator is intended for use with compatible St. Jude Medical temperature controlled ablation catheters for creating endocardial lesions to treat cardiac arrhythmias (i.e. supraventricular tachycardias, and atrial flutter). The generator is limited to 100 watts when used with the Therapy™ Dual 8™ Ablation Catheters.
P050007/S004 **3/23/07** **Real-Time**	StarClose™ SE Vascular Closure System	Abbott Vascular Devices Redwood City, CA 94063	Approval for design changes to the StarClose Vascular Closure System (VCS). The device, as modified, will be marketed under the trade name StarClose™ SE Vascular Closure System and is indicated for the percutaneous closure of common femoral artery access sites while reducing times to hemostasis and ambulation, in patients who have undergone diagnostic or interventional endovascular catheterization procedures utilizing a 5F or 6F procedural sheath and for the percutaneous closure of common femoral artery access sites while reducing time to dischargeability in patients who have undergone diagnostic endovascular catheterization procedures utilizing a 5F or 6F procedural sheath.

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P050018/S001 **3/7/07** **Real-Time**	AngioSculpt® Scoring Balloon Catheter	AngioScore, Inc. Fremont, CA 94538	Approval for minor changes to the strain relief and catheter shaft.
P860019/S219 **3/2/07**	Maverick Monorail PTCA Catheter System	Boston Scientific Cardiovascular Maple Grove, MN 55311	Increase in a parameter limit for the proximal laser weld process.
P930038/S049 **3/29/07**	Angio-Seal™ Vascular Closure Device	St. Jude Medical, Inc. Maple Grove, MN 55330	Change to the vacuum drying process and a change to the environmental conditions of the manufacturing facility.